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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,920	12/28/2006	Philip J. Simpson	ICUMM.376A	1318

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EXAMINER

BOSWORTH, KAMI A

ART UNIT	PAPER NUMBER
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3767

NOTIFICATION DATE	DELIVERY MODE
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09/08/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No. 10/584,920	Applicant(s) SIMPSON ET AL.	
	Examiner KAMI A. BOSWORTH	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-10 and 31-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-10 and 31-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/18/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/18/2009 has been entered. As directed by the amendment submitted along with the request, claims 1, 2, 10, 35, and 38 have been amended and claims 3-5 and 11-30 remain cancelled; thus, claims 1, 2, 6-10, and 31-42 are presently pending in this application.

Response to Arguments

2. Applicant's arguments with respect to claims 1, 2, 6-10, and 31-42 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 6-10, and 31-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doyle (PG PUB 2003/0136932) in view of Patzer (US Pat 5,578,059).

5. Re claim 1, Doyle discloses a valved male luer medical connector 10 (Fig 1) comprising: a male luer portion 104 (Fig 22; equivalent to male luer portion 16 in Fig 1) in a distal side of the connector, the male luer portion comprising interior and exterior surfaces and a bore extending between the interior and exterior surfaces (as seen in Fig 22), a female luer end portion (as seen in Fig 1) in a proximal side of the connector and a channel 124 (Fig 22) for the transfer of fluids between the male luer portion and the female luer end portion (Para 50), a valve member 154 (Fig 22) movable between a closed position (as seen in Fig 22) and an open position (as seen in Fig 23), the valve member comprising a proximal first portion (best seen in Fig A below) and a second portion (best seen in Fig A below) distal from the first portion, the first and second portions of the valve member being configured to move generally longitudinally between the closed and open positions such that a proximal end of the first portion is positioned closer to the female luer end portion in the open position than in the closed position (as seen in Fig 22,23; Para 50), the second portion being positioned at least partially within the male luer portion (as best seen in Fig A below) in the closed position, the valve member further comprising a plug portion 160 (Fig 22) distal from the second portion, the plug portion having a distal end (as seen in Fig 22), the plug portion being closed-ended on the distal end thereof in both the open and closed positions such that fluid is prevented from flowing through the distal end of the plug portion in both the open and closed positions (as seen in Fig 22,23; Para 50), and the plug portion being configured

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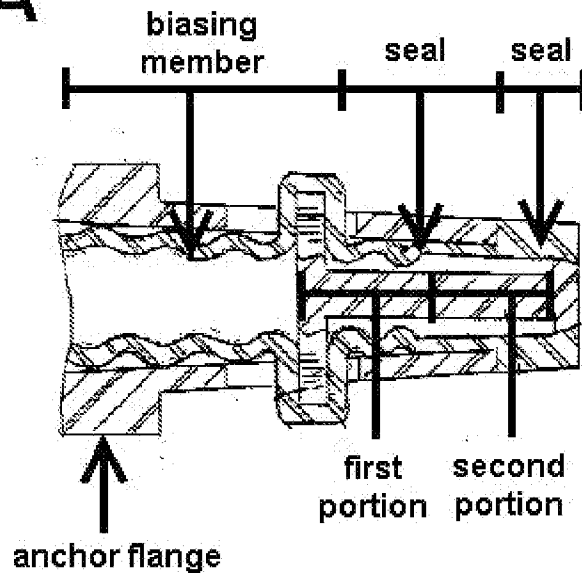
to engage the interior surface of the male luer portion to form a seal such that the closed end of the plug portion is generally flush with a distal end of the exterior surface of the male luer portion in the closed position (as seen in Fig 22), a seal (portion of 160 distal to flange 156; best seen in Fig 22 and A below) extending generally around a portion of the second portion of the valve member (as seen in Fig A below), a biasing member (portion of 160 proximal to flange 156; best seen in Fig 22 and A below) configured to bias the valve member toward the closed position (Para 50), at least a portion of the biasing member generally surrounding at least a portion of the first proximal portion of the valve member (as seen in Fig A below), and an actuating member 158 (Fig 22) extending distally into a region near the exterior surface of the male luer portion in the closed position (as seen in Fig 22), the actuating member being fixed to and unitary with the valve member (as seen in Fig 22), and the actuating member being configured to actuate the valve member from the closed to the open position when a female luer end portion of a medical accessory is advanced into the distal side of the connector such that fluid is permitted to flow around the closed distal end of the plug portion and through the bore extending between the interior and exterior surfaces of the male luer portion in the open position (Para 50), and wherein the actuating member, the first proximal portion of the valve member, and the second portion of the valve member are configured to be non-deformable upon contact with the female luer end portion of the medical accessory (Para 50; as seen in Fig 7). Within this embodiment, Doyle teaches that the valve member is discrete and non-unitary with the biasing member and the seal, but does not teach that the valve all three are discrete

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non-unitary components. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form each of the valve member, seal, and biasing member as discrete non-unitary components, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177,179. Furthermore, Doyle does not disclose that the second portion of the valve member encloses a first generally longitudinal fluid pathway and a second generally transverse fluid pathway that are in fluid communication with each other. Patzer, however, teaches a valve member 26 (Fig 1,4) generally enclosing a first generally longitudinal fluid pathway 36 (Fig 1,4) and a second generally transverse fluid pathway (as seen in Fig 1,4) being in fluid communication with one another such that fluid is permitted to flow through the generally transverse fluid pathway (as seen in Fig 4) for the purpose of permitting fluid communication between two devices (Col 3, Lines 12-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Doyle to include a longitudinal and transverse fluid pathway within the valve member, as taught by Patzer, for the purpose of permitting fluid communication

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between two devices (Col 3, Lines 12-17).

Fig A

6. Re claim 2, Doyle discloses that the distal side of the connector comprises an outer threaded sheath 32 (as seen in Fig 1), the actuating member including a portion positioned between the outer threaded sheath and the male luer portion (as seen in Fig 22).

7. Re claim 6, Doyle discloses that the valve member is integrally formed with the female luer end portion (via 104 as seen in Fig 14).

8. Re claim 7, Doyle discloses a housing portion 102 (as seen in Fig 14), wherein the valve member includes an anchor flange (best seen in Fig A above) extending outwardly toward an inner surface of the housing portion (as seen in Fig 14).

9. Re claim 8, Doyle discloses that the housing portion is coupled to the male luer portion for movement therewith relative to the valve member (as seen in Fig 14; Para 45).

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10. Re claim 9, Doyle discloses that the male luer portion engages the anchor flange when the valve member is in the closed position and the male luer portion is spaced from said anchor flange when the valve member is in the open position (as seen in Fig 14, the male luer portion both engages the anchor flange and is spaced from said anchor flange in both positions).

11. Re claim 10, Doyle discloses that the housing portion 102' (as seen in Fig 18) terminates at an end region adjacent the female luer end portion (as seen in Fig 18), and the biasing member includes a compression spring (Para 45,50) located within the housing portion between the end region and the outer anchor flange (as seen in Fig 14).

12. Re claim 31, Doyle discloses, in a separate embodiment, a radially extending member 60 (Fig 9) forming a transition between the first and second portions of the valve member. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a radially extending member for the purpose of aiding in movement of the valve (Para 40-43).

13. Re claim 32, Doyle discloses that the biasing member is a compression spring (Para 45,50).

14. Re claim 33, Doyle discloses, in a separate embodiment, that sleeve 60 (Fig 9) acts as an actuating member and that the biasing member 66 (Fig 9) does not contact the actuating member or the second portion of the valve member (as seen in Fig 9). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a biasing member that does not contact the actuating member or the

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second portion of the valve member for the purpose of aiding in movement of the valve (Para 40-43).

15. Re claim 34, Doyle discloses that the biasing member is contained entirely within an interior region of the connector (as seen in Fig 22).

16. Re claim 35, Doyle does not explicitly disclose that the distal end of the plug portion is narrower than any portion of the second portion of the valve member.

However, it would have been an obvious matter of design choice to modify Doyle to include a distal end of the plug portion that is narrower than any portion of the second portion of the valve member since applicant has not disclosed that having a narrower distal end of the plug portion solves any stated problem or is for any particular purpose and it appears that the device would perform equally well with either designs.

Furthermore, absent a teaching as to the criticality that the distal end of the plug portion be narrower than any portion of the second portion of the valve member, this particular arrangement is deemed to have been known by those skilled in the art since the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement. In *re Kuhle*, 526 F.2d 553,555,188 USPQ 7, 9 (CCPA 1975). Furthermore, it would have been an obvious matter of design choice to form the distal end of the plug portion narrower than any portion of the second portion of the valve member since such a modification would have involved a mere change in the form or shape of a component. A change in form or shape is generally recognized as being within the level of ordinary skill in the art. In *re Dailey*, 149 USPQ 47 (CCPA 1976).

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17. Re claim 36, Doyle does not explicitly disclose that the distal end of the plug portion is narrower than any portion other portion of the valve member. However, it would have been an obvious matter of design choice to modify Doyle to include a distal end of the plug portion that is narrower than any other portion of the valve member since applicant has not disclosed that having a narrower distal end of the plug portion solves any stated problem or is for any particular purpose and it appears that the device would perform equally well with either designs. Furthermore, absent a teaching as to the criticality that the distal end of the plug portion be narrower than any other portion of the valve member, this particular arrangement is deemed to have been known by those skilled in the art since the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement. In *re Kuhle*, 526 F.2d 553,555,188 USPQ 7, 9 (CCPA 1975). Furthermore, it would have been an obvious matter of design choice to form the distal end of the plug portion narrower than any other portion of the valve member since such a modification would have involved a mere change in the form or shape of a component. A change in form or shape is generally recognized as being within the level of ordinary skill in the art. In *re Dailey*, 149 USPQ 47 (CCPA 1976).

18. Re claim 37, Doyle discloses that the seal is stationary when the valve member moves (as seen in Fig 22,23).

19. Re claim 38, Doyle discloses that the plug is non-deformable (Para 50).

20. Re claim 39, Doyle discloses all the claimed features except that the second generally transverse fluid channel consists of side openings on opposing sides of the

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valve member. Patzer, however, teaches a generally transverse fluid channel that consists of side openings on opposing sides of the valve member (as seen in Fig 1,4) for the purpose of permitting fluid communication between two devices (Col 3, Lines 12-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Doyle to include side openings on opposing sides of the valve member, as taught by Patzer, for the purpose of permitting fluid communication between two devices (Col 3, Lines 12-17).

21. Re claim 40, Doyle discloses an outer housing 102',102 (Fig 18) made of two discrete parts coupled together (as seen in Fig 18).

22. Re claim 41, Doyle discloses a second seal positioned near the first proximal portion of the valve member (as seen in Fig A above).

23. Re claim 42, Doyle discloses all the claimed features except that the first proximal portion generally encloses a fluid channel positioned inside the first proximal portion. Patzer, however, teaches a fluid channel 36 (Fig 1,4) that runs throughout the entirety of the valve member (as seen in Fig 1,4) for the purpose of permitting fluid communication between two devices (Col 3, Lines 12-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Doyle to include a fluid channel inside the first proximal portion, as taught by Patzer, for the purpose of permitting fluid communication between two devices (Col 3, Lines 12-17).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAMI A. BOSWORTH whose telephone number is (571)270-5414. The examiner can normally be reached on Monday - Thursday, 7:00 am to 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. A. B./
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767